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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,314	09/25/2001	Sang Yup Lee	HYLEE55.001AUS	1325
20995	7590	10/20/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			LY, CHEYNE D	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/963,314

Applicant(s)

LEE ET AL.

Examiner

Cheyne D Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 3-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/25/01</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traversal of Group I, claims 1 and 2, filed July 07, 2004, is acknowledged.
2. The traversal is on the ground(s) that it would not be unduly burdensome to perform a search on all the claims together because all the claims are directed to the various embodiments of the same novel codon scanning algorithm, and the claim language clearly identifies the relationship between the aspects of the claimed subject matter. Applicant's claim amendment has been acknowledged. However, Applicant's arguments have been found to be not persuasive as discussed below. Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the DNA chip of Group III can be made with the process of Group II, or alternatively can be made by the distinct process of in-situ synthesis of probes immobilized thereon.
3. Inventions [II and III] and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the DNA chip of Group II or III can be practiced in the method for detecting genetic mutations as in Group IV, or alternatively, in the process of differential gene expression corresponding to a specific stimulus.

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4. This lack of overlapping searches documents the undue search burden if they were search together.
5. The requirement is still deemed proper and is therefore made FINAL.
6. Claims 1 and 2 are examined on the merits.

OBJECTIONS

7. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (Page 2, Line 18). Applicant(s) is/are required to delete the embedded hyperlink and/or other form of browser-executable code, or inactivate the hyperlink. See MPEP § 608.01.
8. The title of the invention is not descriptive because the instant title is directed to a "DNA chip using codon scanning algorithm" while the elected invention is directed to "A process for preparing oligonucleotide using codon scanning algorithm". A new title is required that is clearly indicative of the invention to which the claims are directed.
9. The abstract of the disclosure is objected to because the instant is more 150 words. Correction is required. Applicant is required to submit an abstract commencing on a separate sheet of paper. See MPEP § 608.01(b).

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
11. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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12. Specific to claim 1, lines 1-2, the preamble recites "using codon scanning algorithm", however, steps (i) and (ii) do not recite the use of any codon scanning algorithm which causes said claim to be vague and indefinite. Claim 1 is unclear as to whether the preamble or steps (i) and (ii) control the metes and bounds of the claimed invention. Clarification of the metes and bounds is required. Claim 2 is rejected for being dependent from claim 1.

13. Specific to claim 1, lines 5-6, the phrase "rest of...normal individuals" causes claim 1 to be vague and indefinite because the phrase "rest of sequences are remained same" is unclear. Is the phrase "rest of sequences are remained same" being directed to the mutated codon, probes of 7 nucleotides or more, or probes of less than 7 nucleotides? Further, the phrase "normal individuals" causes claim 1 to be unclear because the antecedent basis for said phrase is not clear. Are the mutated codons, probes of 7 nucleotides or more, or probes of less than 7 nucleotides "normal individuals"? The same issue is present in claim 2, lines 1-9. Clarification of the metes and bounds is required.

CLAIM REJECTIONS - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hacia (January 1999) taken with Stabinsky (US 4739044 A).

17. Due to the vague and indefinite issues of claims 1 and 2 discussed above, the claim limitations of claims 1 and 2 have been interpreted as broad as reasonable in the instant prior art rejection.

Don't say as they already are in prior art

18. Hacia discloses a method of mutational analysis using oligonucleotide microarrays comprising selecting the 37 known mutations in the coding region of CFTR (codon), as well as all possible single-nucleotide substitutions (page 42, column 2, lines 25-28). An array designed to interrogate both strands of a target of length N for all possible single nucleotide substitutions would consist of 8 N probes, usually 20-25 nt. There are 4 N probes (often termed 'A', 'C', 'G', and 'T' probes). Probes are designed such that the location of the interrogated target basis is in the center-most position. For a 10-kb DNA target, 80,000 probes (normal) are needed to interrogate for all possible single nucleotide substitutions (page 43, Gain of hybridization signal approach §, columns 1-2). The substitution scheme for each position is illustrated in Figure 2 (page 43), as in instant claims 1 and 2.

19. However, Hacia does not disclose the limitation of an amine group is linked to 3' terminus of the probe.

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20. Stabinsky discloses an improvement for the generic attachment of reporter groups such as primary amines to the 3' end polynucleotides for the detection and quantitation by hybridization assays (Abstract etc., column 1, lines 10-23, and column 2, lines 50-52), as in instant claim 1.

21. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvement emphasized by Stabinsky to utilize the polynucleotides labeled with amine group in microarray type of hybridization assays as taught by Hacia. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use a method of mutational analysis using oligonucleotide microarrays with polynucleotides labeled with a 3' amine group as taught by Hacia and Stabinsky.

CONCLUSION

22. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

23. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete

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service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

24. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

C. Dune Ly
8/27/04



MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600